



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; ABCD Study® Data Use

Certification (National Institute on Drug Abuse)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Elizabeth A. Hoffman Senior Scientific Program Manager, Division of Extramural Research, National Institute on Drug Abuse, 3WFN Room 09C75 MSC 6021, Gaithersburg, MD 20877, or call non-toll-free number (301) 594-2265 or E-mail your request, including your address to: elizabeth.hoffman@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance

of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: ABCD Study® Data Use Certification, 0925-NEW, exp., date XX/XX/XXXX, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this proposal is to inform data requestors about terms and conditions for using data generated by the Adolescent Brain Cognitive Development^(SM) (ABCD) Study and to obtain signed agreements from requestors and their institutional officials attesting to their commitment to abide by the data use terms and conditions. These include using data for research purposes; adhering to human subjects research requirements; not distributing the data to non-authorized users; minimizing risk of participant identifiability; using data ethically and responsibly; and keeping the data secure. Users must include a brief description of their research project and submit their signed data use agreements to the data repository to gain access to the ABCD Study® data. Users who plan to conduct research studies specifically on American Indian/Alaska Native (AI/AN) populations must submit an additional signed data use certification.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,000.

Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hour
Individuals (standard DUC form)	1800	1	1	1800
Individuals (additional AI/AN DUC form when needed)	200	1	1	200
TOTAL		2000		2,000

Lanette A. Palmquist,

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National Institutes of Health.

[FR Doc. 2023-08743 Filed: 4/25/2023 8:45 am; Publication Date: 4/26/2023]